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| (54) Title: AN ADHESIVE AGENT AND USE OF SUCH ADHESIVE AGENT (57) Abstract Adhesive compositions comprising a water-dispersible polyester shows a very rapid water absorption and improves the wet tack and is, at the same time, resistant to disintegration upon contact with body fluids. | | |

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TITLE

An Adhesive Agent and Use of Such Adhesive Agent

FIELD OF THE INVENTION

The invention relates to a pressure sensitive adhesive composition suitable for
5 application to human or animal skin, to a method for preparing such adhesives
and the use of such adhesive for the preparation of a wound dressing or a
adhesive wafer for an ostomy appliance or the use of the adhesive agent for
securing of and sealing around ostomy bandages, for securing wound dressings,
for securing of devices for collecting urine, wound-drainage bandages, orthoses
10 and prostheses and for protection skin areas and parts of the body against
pressure, impacts and friction and to wound dressings or ostomy appliances
comprising such adhesive composition..

BACKGROUND OF THE INVENTION

Various skin adhesive agents are used today for the above mentioned purposes.

15 A very widespread embodiment of skin adhesive agents comprises a
self-adhesive elastomeric matrix, in which water-absorbing, swelling particles, the
so-called hydrocolloids, are dispersed.

Adhesive compositions comprising hydrocolloids have been known for many
years. US. patent No. 3,339,549 discloses a blend of a rubbery elastomer such
20 as polyisobutylene and one or more water soluble or water swellable
hydrocolloids such as a powdery mixture of pectin, gelatine and
carboxymethylcellulose. The adhesive mass has a water-insoluble film applied to
one surface. A composition of this type is available commercially from E.R.
Squibb & Sons Inc. under the trademark "Stomadhesive" and is used as a skin
25 barrier around stomas to prevent skin breakdown by the corrosive fluids
discharged by the stoma and is also used for adhesive wafers for ostomy
appliances.

In adhesive compositions of this type, the polyisobutylene is responsible for provision of the adhesive properties and the dispersed hydrocolloid powders absorb fluid and render the adhesive agent capable of also adhering to moist skin (wet tack). These compositions are also gaining increasing acceptance as wound dressings for dermal ulcers, burns and other exuding wounds.

One major problem which has been encountered with conventional adhesive compositions comprising hydrocolloids is their susceptibility to breakdown upon exposure to body fluids. When the compositions are used as skin barriers, e.g., around stomas, absorption of fluid is desirable, but excessive swelling of the hydrocolloids upon absorption causes the composition to lose its integrity opening for leaks and the barrier must be replaced more often than is desirable from a skin protection point of view, and very often, a residue remains on the skin, which in many cases is difficult to remove.

When bandaging wounds, contact with the wound exudate will in a similar way effect a disintegration of the adhesive agent which means that when the bandage is changed remnants will be left in the wound, which remnants may affect the wound-healing process. Besides during use leakage may arise which partly means reduced time of use, partly may increase the risk of contaminating the wound with bacteria or other microorganisms.

Adhesive agents are also used for securing devices, such as uridomas, for collecting the urine from incontinent men. Disintegration of the adhesive agent due to contact with urine will again mean a risk of leakage and a reduction of the time of use.

Adhesive agents are also employed for securing orthoses and prostheses (e.g. breast prostheses) and for protection of skin areas or parts of the body against pressure, impact and friction. In these cases it is primarily the secretion of sweat which may cause swelling and disintegration of the adhesive agent. When

removing the adhesive agent remnants will be left on the skin, involving the inconveniences earlier mentioned.

A number of attempts have been made to improve the integrity of adhesive compositions.

5 As a method for improving the adhesive integrity the use of hydrocolloids has been described which, in themselves, are cross-linked (e.g. cross-linked carboxymethylcellulose (CMC), cross-linked dextrane and other water-absorbing, but insoluble hydrocolloids). They will not dissolve due to the cross-linked structure. During the swelling process the individual particles will, therefore,
10 obtain a gel-like structure, but no coherent gel could be formed since the macromolecules of the cross-linked hydrocolloids are locked in the gel network constituted by the individual particles. Due to the lack of a coherent gel, the cross-linked hydrocolloids will be leached out and suspended in the body fluids and the effect on the integrity of the swelled adhesive, therefore, is limited.

15 Alternatively, it has been tried to increase the integrity of the swelled adhesive agent by increasing the cohesion of the elastomeric phase (as described in several of the prior art patents referred to). The elastomeric phase, therefore, will not so easily be split by the expanding hydrocolloids during the swelling process. This process, however, has a number of drawbacks:

20 - The rate of water absorption and thus the "wet tack" of the adhesive agent will be reduced.

- By strengthening the cohesion the elastomeric matrix will have stronger elastic properties. When the hydrocolloids absorb water and swell, this will enhance an increase in the dimensions of the adhesive agent. Due to the elastic properties of
25 the matrix, the tensions occurring in the adhesive agent cannot be relaxed by plastic deformation. Instead pleats may occur in the adhesive agent around the

swelled area. In these pleats the adhesive agent will loose contact with the skin exposed to the body fluids, and a risk of leakage arises.

US. Patent Nos. 4,192,785 and 4,551,490 describe incorporating into an adhesive composition of a cohesive strengthening agent such as a natural or
5 synthetic fibrous material, finely divided cellulose, cross-linked dextran, cross-linked carboxymethylcellulose or a starch-acrylonitrile graft copolymer. The cohesive strengthening agent is stated to control the rate of hydration of the composition thereby increasing the resistance against breakdown by body fluids.

US. Patent No. 4,477,325 describes incorporation of a mixture of a copolymer
10 resin of ethylene and vinyl acetate (EVA) into the adhesive composition. After mixing and moulding, the composition is subjected to ionising radiation to form a cross-linked polymer network of the EVA or comprising EVA and another cross-linked resin. The cross-linked matrix is said to provide a controlled swelling.

15 US. Patent No. 4,496,357 describes the incorporation of fumed silica into adhesive compositions to control swelling.

EP No. 0 122 344 B1 describes incorporation of one or more natural or synthetic polymers capable of developing elastomeric properties when hydrated, such as gluten and long chain polymers of methyl vinyl ether/maleic acid, into the
20 adhesive composition. The adhesive composition is stated to be resistant to erosion by moisture and body fluids.

EP patent No. 0 340 945 B1 describes incorporation of some polycationic hydrocolloid particles into a hydrocolloid composition. The mixture of polycationic, polyanionic and neutral hydrocolloids is stated to provide increased
25 integrity without a concomitant decrease in absorbing capacity.

Another major problem for conventional adhesive compositions comprising hydrocolloids is their limited capability in adhering to moist body surfaces. There is particularly a need for an improved adhesive composition having an enhanced adhesion to moist skin in the management of ostomy patients, as it is often
5 difficult to keep the skin around stomas completely dry during replacement of an ostomy appliance.

In existing adhesive agents the surface of the adhesive is consisting of the self-adhesive elastomeric matrix while the hydrocolloids are located embedded beneath in the elastomeric matrix. In order to absorb moisture, the water thus
10 needs to penetrate through the elastomeric matrix before reaching the water absorbing hydrocolloids. This retards the water-absorption and causes that the adhesive agent does not have an immediately adhesion to wet surfaces (wet tack).

Suitable hydrocolloids are naturally occurring hydrocolloids such as guar, locust
15 bean gum (LBG), pectin, alginates, gelatine, xanthan or karaya, semisynthetic hydrocolloids such as cellulose derivatives (e.g. salts of carboxymethylcellulose, methylcellulose and hydroxypropylmethylcellulose), sodium starch glycolate and synthetic hydrocolloids such as polyvinylalcohol, polyethylene glycol or polyacrylates.

20 Skin problems associated with an ostomy are differing from skin problems generally associated with adhesives for skin (dressings or plasters) as the adhesives of ostomy appliances are placed permanently at the same site during long periods of time (chronical irritation) whereas other adhesives for skin are normally only placed at the same site for a short period of time.

25 European Patent publication No. EP 0 017 401 A1 discloses articles of manufacture having adhesive properties useful for, for example, protective plasters or dressings or as rings, washers or the like in surgical appliances such as ostomy appliances comprising a plastics matrix comprising the product

resulting from heating together one or more polyhydric alcohols and gelatine and/or naturally occurring high molecular weight polysaccharide gum and/or a resin which is a copolymer and a vinyl ether and an organic acid anhydride and/or its corresponding free acid. Polyvinylpyrrolidone resin may be added as a
5 tack modifier.

European Patent publication No. EP 0 343 807 A2 discloses absorptive adhesive dressing with controlled hydration containing about 30-65% polyisobutylene, 10-30% polyvinylpyrrolidone, 2-20% modified starch, 2-20% pectin, 0.1-10% acrylic polymer and 0-1% fibre.

10 European Patent publication No. EP 0 063 898 discloses a microporous tape comprising a porous backing layer and a microporous adhesive layer including a rubbery elastomer such as polyisobutylene, one or more water swellable hydrocolloids and other optional substances. A copolymer of polyvinylpyrrolidone and vinylacetate may be used as a tackifier.

15 Thus, there is still a need for an adhesive composition showing a very rapid water absorption and retention in order to improve wet tack and which is, at the same time, resistant to disintegration upon contact with body fluids.

It has surprisingly been found that adhesive compositions comprising a water-dispersible polyester shows a very rapid water absorption and improves
20 the wet tack and is, at the same time, resistant to disintegration upon contact with body fluids.

BRIEF DESCRIPTION OF THE INVENTION

The present invention relates to a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a water dispersible
25 polymer.

The invention also relates to a method for preparing a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a water dispersible polymer and to the use of such adhesive for the preparation of a wound dressing or a adhesive wafer for an ostomy appliance or the use of
5 the adhesive agent for securing of and sealing around ostomy bandages, for securing wound dressings, for securing of devices for collecting urine, wound-drainage bandages, orthoses and prostheses and for protection skin areas and parts of the body against pressure, impacts and friction and to wound dressings or ostomy appliances comprising such adhesive composition.

10 DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a) a water dispersible polymer, b) one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, and/or one or more physically
15 cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, and/or one or more polyethylene glycols and/or glycerol; c) optionally a butene polymer or copolymer, d) optionally a tackifying resin which may be partly or totally hydrogenated, e) optionally a microcrystalline wax, f) optionally a plasticizer, g) optionally one or more hydrocolloids and h) optionally a
20 pigment.

By introducing a water dispersible polymer in a self-adhesive elastomeric matrix an improved adhesion in moist environment is achieved. This is ascribed to the fact that the water dispersible polymer is present at the surface of the adhesive agent and thus is able to cause an immediately absorption of water. The
25 water-absorbing polymer furthermore remains sticky after having absorbed water which is in contrast to the non-absorbing elastomers used in conventional skin friendly adhesives and hence, a better adhesion over longer periods of time is obtained.

The pressure sensitive adhesive composition of the invention typically comprises 10-50% of a water dispersible polymer, 10-70% of one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, and/or one or more physically cross-linked elastomers selected from 5 block-copolymers comprising styrene and one or more olefins, and/or one or more polyethylene glycols and/or glycerol; 0-15% of a butene polymer or copolymer, 0-30% of a tackifying resin which may be partly or totally hydrogenated, 0-10% of a microcrystalline wax, 0-10% of a plasticizer, 0-50% of one or more hydrocolloids and 0-5% of a pigment.

- 10 The water dispersible polymer is preferably a water-absorbing elastomer and more preferred a water-dispersible branched polyester.

The use of branched water-dispersible polyester in adhesive agents gives the following advantages:

- The adhesive agent shows a superior adhesion in moist environments by having 15 an immediately absorption of water giving a better wet tack as compared to conventional adhesive agents based on non-absorbing self-adhesive elastomers. The branched water-dispersible polyester is also contributing by giving a good adherence over a longer periods of time since the stickiness of the elastomer is retained even after absorption of body fluids.

- 20 - The adhesive agent is easily removed by washing due to the water-dispersibility of the polyester in tap water, but the adhesive agent is not affected by body fluids. The body fluids are ionic solutions in which the polyester component is not dispersible. Adhesive residues left on the skin can thus be removed very easily using tap water.

25

Suitable water-dispersible branched polyester are polyesters having the following physical properties: a Brookfield Thermosel viscosity at 177°C of 1,000-500,000 mPa.s, more preferred 1,000-50,000 mPa.s, and preferably of 2,000-8,000, a

ring & ball softening point of 50-150°C more preferred of 80-90°C, a penetration hardness as determined according to ASTM D 5 of 5-50 dmm, preferably about 30 dmm and a glass transition temperature T_g according to ASTM D 3418 of from 5 to -10 °C, preferably about -5°C

5

A reduction or even omission of the amount of hydrocolloids is rendered possible as the branched water-dispersible polyester contributes to the absorption. A reduction of the amount of hydrocolloids improves the stability of the adhesive due to the reduction of the disintegration caused by the considerable swelling of the
10 hydrocolloids in conventional skin friendly adhesives upon absorption of body fluids.

When hydrocolloids are present, suitable hydrocolloids are the ones mentioned above.

Pigments may be used as fillers or for dyeing the adhesives of the invention. Suitable
15 pigments are pigments conventionally used in adhesive compositions, e.g. titanium dioxide or zinc oxide. Zinc oxide offers the advantage of showing an antibacterial effect.

Preferred adhesives according to the invention are e.g. adhesives comprising branched water-dispersible polyester and amorphous poly-alpha-olefines and having the composition:

- 0 - 10 % Ethylene/1-butene Copolymer (e.g. Hüls Vestoplast 520)
- 5 20 - 40% Propene/1-hexene Copolymer (e.g. Eastman Eastoflex D-127)
- 0 - 10% Triblock copolymer (e.g. SIS, such as Kraton® D1107 from Shell Chemicals)
- 0 - 15 % Polybutene (e.g. Hyvis 10, Hyvis 2000)
- 0 - 15% Liquid polyterpene-tackyfier (e.g. Goodyear Wingtack 10)
- 10 0 - 15% Hydrogenated poly(hydrocarbon/terpene) tackyfier
(e.g. Goodyear Wingtack 95).
- 0 - 15% Optionally hydrogenated rosin acid and esters thereof
- 0 - 10 % Plastisizer (e.g. dioctyl adipate)
- 10 - 50% Eastman water-dispersible branched polyester (e.g. AQ1045)
- 15 0 - 50% Hydrocolloids (e.g. CMC, Natrosol, Ca-alginat etc.)
- 0 - 5% Pigment, e.g. zinc oxide

Other preferred adhesives according to the invention are e.g. adhesives comprising branched water-dispersible polyester and block copolymers and having the composition:

- 20 0 - 10 % Triblock copolymer (e.g. SIS)
- 10 - 50 % Diblock copolymer (e.g. SI)
- 0 - 10 % Plastisizer (e.g. dioctyladipate)
- 0 - 15 % Tackifier (e.g. liquid polyterpene, hydrogenated
poly(hydrocarbon/terpene)
- 25 0 - 10 % Microcrystalline wax (e.g. Wax Total 40/60 from Total)
- 10 - 50 % Eastman water-dispersible branched polyester (e.g. AQ1045)
- 0 - 50 % Hydrocolloids (e.g. CMC, Natrosol, Ca-alginat etc.)
- 0 - 5% Pigment, e.g. zinc oxide

Further preferred adhesives according to the invention are e.g. adhesives comprising branched water-dispersible polyester and glycerol and having the composition:

10 - 50 % Glycerol

5 10 - 50 % Eastman water-dispersible branched polyester (e.g. AQ1045)

0 - 50 % Hydrocolloids (e.g. CMC, Natrosol, Ca-alginat etc.)

0 - 5% Pigment, e.g. zinc oxide

Yet further preferred adhesives according to the invention are e.g. adhesives comprising branched water-dispersible polyester and polyethylene glycol (PEG)

10 and having the composition:

10 - 50 % Polyethylene glycol (e.g. PEG 400)

10 - 50 % Eastman water-dispersible branched polyester (e.g. AQ1045)

0 - 50 % Hydrocolloids (e.g. CMC, Natrosol, Ca-alginat etc.)

0 - 5% Pigment, e.g. zinc oxide

15 The olefin component of the block-copolymers comprising styrene and one or more olefins is preferably a diene, especially a polybutadiene such as butadiene, isobutylene or isoprene.

In a second aspect, the invention relates to a method for preparing a pressure sensitive adhesive composition suitable for application to human or animal skin
20 comprising a water dispersible polymer, one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, polyethylene glycols and glycerol; optionally a butene polymer or copolymer, optionally a tackifying resin which may be partly or
25 totally hydrogenated, optionally a microcrystalline wax, optionally a plasticizer, optionally one or more hydrocolloids and optionally a pigment, characterised in that the polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins,

polyethylene glycols and glycerol is mixed, whereafter the water dispersible polyester is admixed and mixed until homogeneity, a plasticizer is optionally admixed, and optionally one or more hydrocolloids are admixed under a reduced pressure whereafter the adhesive agent is removed from the mixer and optionally
5 pressed into 1 mm thin plates between two sheets of release paper.

The invention relates to a further method for preparing a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a water dispersible polymer, one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, one or more physically
10 cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, polyethylene glycols and glycerol; optionally a butene polymer or copolymer, optionally a tackifying resin which may be partly or totally hydrogenated, optionally a microcrystalline wax, optionally a plasticizer, optionally one or more hydrocolloids and optionally a pigment, characterised in
15 that the polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, polyethylene glycols and glycerol; a butene polymer and/or a tackifying resin which may be partly or totally hydrogenated and/or a microcrystalline wax and/or
20 a plasticizer is(are) optionally admixed and mixed until homogeneity, the water dispersible polyester is admixed and mixed until homogeneity, and optionally one or more hydrocolloids are admixed under a reduced pressure whereafter the adhesive agent is removed from the mixer and optionally pressed into 1 mm thin plates between two sheets of release paper.

25 In a third aspect the invention relates to the use of a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a water dispersible polymer, one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and
30 one or more olefins, polyethylene glycols and glycerol; optionally a butene

polymer or copolymer, optionally a tackifying resin which may be partly or totally hydrogenated, optionally a microcrystalline wax, optionally a plasticizer, optionally one or more hydrocolloids and optionally a pigment for securing of and sealing around ostomy bandages, for securing wound dressings, for securing of
5 devices for collecting urine, wound-drainage bandages, orthoses and prostheses and for protection skin areas and parts of the body against pressure, impacts and friction.

In a further aspect, the invention relates to the use of a water dispersible polyester for the preparation of a pressure sensitive adhesive composition
10 suitable for application to human or animal skin, said adhesive comprising one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, polyethylene glycols and glycerol; optionally a butene polymer or copolymer, optionally a tackifying resin which may be partly or totally hydrogenated, optionally a microcrystalline wax, optionally a
15 plasticizer, optionally one or more hydrocolloids and optionally a pigment.

In still further aspects, the invention relates to wound dressings or ostomy appliances comprising an adhesive composition according to the invention. Such wound dressings or ostomy appliances resemble conventional wound dressings or ostomy appliances apart from the substitution of the adhesive of a dressing or
20 ostomy adhesive plate or wafer with an adhesive according to the invention.

The invention is explained more in detail with reference to the below examples disclosing preferred embodiments of the invention. The examples are thus not to be considered limiting of the scope of the invention as set forth in the appended claims.

25 MATERIALS AND METHODS

AQ1045 from Eastman. A branched water-dispersible polyester.

AQ1350 from Eastman. A branched water-dispersible polyester.

Kraton® D 1107 from Shell Chemical Company. Styrene-isoprene-styrene copolymer (SIS) having a molecular weight of 212,000-260,000 as determined by GPC.

Vector® 4114 from Exxon: Styrene-isoprene-styrene copolymer (SIS) having a molecular weight of 130,000 and a content of diblock copolymer of 40% and 15% styrene.

LVSI 101 from Shell Chemical Company. Styrene-isoprene diblock copolymer (SI) having a molecular weight of 30,000 as determined by GPC

Diocyladipate from International Speciality Chemicals Ltd. A plastisizer.

10 METALYN 200, a methyl ester of rosin from Hercules

Eastoflex E1003, E 1060 and E 1200 from Eastman. propylene-ethylene copolymers.

Eastoflex D127 from Eastman. A propylene/1-hexene copolymer

Vestoplast 704, 708 and 750: amorphous propylene-rich poly- α -olefins from Hüls

15 Chemie

Wingtack 10 from Goodyear. A liquid polyterpene tackyfier resin

Arkon P90: A fully saturated alicyclic light coloured hydrocarbon resin having molecular weight of 650 from ARAKAWA Chemical Industries

Arkon P70: A fully saturated alicyclic light coloured hydrocarbon resin having molecular weight of 570 from ARAKAWA Chemical Industries

Foral 85: Foral 85-E, A hydrogenated Rosin Glycerol Ester from HERCULES Inc.

Foral AX-E: A hydrogenated Rosin from HERCULES Inc.

Glycerol.

PEG 400 from Hoechst. Polyethylene glycol.

Blanose 9H4XF from Hercules. Sodium carboxymethylcellulose.

Pectin USP/100 from Copenhagen Pectin.

Klucel HXF EP. Hydroxypropyl cellulose.

5 Gelatine P.S.98.240.233 from ED. Geistlich Sohne AG

Zink Oxide Pharma from Hoechst AG.

EXPERIMENTAL PART

Preparation of the adhesives according to the invention

Example 1

- 10 An adhesive agent having the composition stated in Table 1 was prepared in a Z-blade mixer. Before the mixing, the mixing chamber was heated to 140°C by means of an oil heater. AQ1045, Eastoflex D127, Eastoflex E1003, dioctyladipate and the hydrocolloids were weighed out separately. Firstly Eastoflex D127 and E1003 were mixed for 15 minutes. AQ1045 was added and
- 15 the mixing continued for 10 minutes. Dioctyladipate was added and mixed for additional 10 minutes. The heat supply was turned off and the mixing chamber was cooled down to 80°C. The hydrocolloids (a mixture of pectin, hydroxypropyl cellulose and gelatine in the ratio 1:1.5:1) were added and the mixing was continued in vacuo until a total mixing time of 60 minutes. The adhesive agent
- 20 was removed from the mixer and pressed into 1 mm thin plates between two sheets of silicon paper in a hydraulic press at 90°C.

Example 2

- An adhesive agent having the composition stated in Table 1 was prepared in a Z-blade mixer. Before the mixing, the mixing chamber was heated to 140°C by
- 25 means of an oil heater. AQ1350, Eastoflex D127, Eastoflex E1003, Wingtack 10 and dioctyladipate were weighed out separately. Firstly Eastoflex D127 and

E1003 were mixed for 15 minutes. AQ1350 and was added and the mixing continued for 10 minutes. Wingtack 10 was added and mixed for additional 10 minutes and finally dioctyladipate was added. The adhesive agent was removed from the mixer and pressed into 1 mm thin plates between two sheets of silicon paper in a hydraulic press at 90°C.

Example 3

An adhesive agent having the composition stated in Table 1 was prepared in a Z-blade mixer. Before the mixing, the mixing chamber was heated to 150°C by means of an oil heater. AQ1045, Kraton D1107, LVSI101, dioctyladipate and the hydrocolloids were weighed out separately. Firstly Kraton and dioctyladipate were mixed at 150°C for 15 minutes. LVSI 101 was added and the mixing continued for 10 minutes. The mixing chamber was cooled down to 130°C and AQ1045 was added and the mixing was continued for an additional 15 minutes. The heat supply was turned off and the mixing chamber was cooled down to 80°C. The hydrocolloids, a mixture of pectin and hydroxypropylcellulose in the ratio 1:1, and finally zinc oxide were added and the mixing was continued in vacuo until a total mixing time of 60 minutes. The adhesive agent was removed from the mixer and pressed into 1 mm thin plates between two sheets of silicon paper in a hydraulic press at 90°C.

Example 4

An adhesive agent was having the composition stated in Table 1 prepared in a Z-blade mixer. Before the mixing, the mixing chamber was heated to 130°C by means of an oil heater. AQ1045 and glycerol and the hydrocolloids were weighed out separately. Firstly AQ1045 and glycerol were mixed at 130°C for 15 minutes. The heat supply was turned off and the mixing chamber was cooled down to 80°C. The hydrocolloids, a mixture of pectin and gelatine in the ratio 1:2, were added and the mixing continued in vacuo until a total mixing time of 40 minutes. The adhesive agent was removed from the mixer and is pressed into 1 mm thin plates between two sheets of silicon paper in a hydraulic press at 90°C.

Example 5

An adhesive agent having the composition stated in Table 1 was prepared in a Z-blade mixer. Before the mixing, the mixing chamber was heated to 130°C by means of an oil heater. AQ1045 and PEG 400 and the hydrocolloids were weighed out separately. Firstly AQ1045 and PEG 400 were mixed at 130°C for 15 minutes. The heat supply was turned off and the mixing chamber was cooled down to 80°C. The hydrocolloids, a mixture of hydroxypropylcellulose and gelatine in the ratio 1:1, were added and the mixing continued in vacuo until a total mixing time of 40 minutes. The adhesive agent was removed from the mixer and pressed into 1 mm thin plates between two sheets of silicon paper in a hydraulic press at 90°C.

Example 6

An adhesive agent having the composition stated in Table 1 was prepared in a Z-blade mixer in the same manner as described in Example 3.

Table 1

| Constituent | Example 1 | Example 2 | Example 3 | Example 4 | Example 5 | Example 6 |
|-----------------|-----------|-----------|-----------|-----------|-----------|-----------|
| AQ1045 | 35 | | 30 | 50 | 40 | 32 |
| AQ 1350 | | 50 | | | | |
| LVSI 101 | | | 29 | | | 25 |
| Kraton D 1107 | | | 5 | | | 5 |
| Doctyladipate | 5 | 5 | 5 | | | 8 |
| Eastoflex D127 | 15 | 15 | | | | |
| Eastoflex E1003 | 10 | 15 | | | | |
| Wingtack 10 | | 15 | | | | |
| Glycerol | | | | 20 | | |
| PEG 400 | | | | | 20 | |
| Blanose 9H4XF | | | | | | |
| Pectin USP/100 | 10 | | 15 | 10 | | 15 |
| Klucel HXF EP | 15 | | 15 | | 20 | 15 |
| Gelatine | 10 | | | 20 | 20 | |
| Zinc oxide | | | 1 | | | |

EXAMPLES 7 - 11

Adhesives compositions according to the invention being suitable as pastes having the compositions stated in Table 2 were prepared in a Z-mixer in the same manner as described in Example 1

5 Table 2

| Constituent | Example 7 | Example 8 | Example 9 | Example 10 | Example 11 |
|------------------|-----------|-----------|-----------|------------|------------|
| Eastoflex E 1003 | 15 | 15 | 15 | 20 | 20 |
| Eastoflex E 1060 | | | | 2.5 | 2.5 |
| AQ 1350 | 35 | 35 | 35 | 35 | 35 |
| Diocetyl adipate | 5 | 5 | 5 | 5 | |
| Metaldyn 200 | | | | | 5 |
| Vestoplast 708 | 10 | 5 | 5 | 2.5 | 2.5 |
| Vestoplast 704 | | 5 | 2.5 | | |
| Vestoplast 750 | 10 | | 2.5 | | |
| Gelatine | 10 | 10 | 10 | 10 | 10 |
| Pectin | 15 | 10 | 10 | 10 | 10 |
| Klucel | | 15 | 15 | 15 | 15 |

EXAMPLES 12 - 21

Adhesive agents having the composition stated in Tables 3-4 were prepared in a Z-blade mixer. Before the mixing, the mixing chamber was heated to 150°C by means of an oil heater. AQ1045, Vector 4114, LVSI 101, Arkon P-90 and the 5 hydrocolloids were weighed out separately. Firstly Vector was mixed at 150°C for 15 minutes. LVSI 101 was added and the mixing continued for 15 minutes. The mixing chamber was cooled to 130°C and Arkon P-90, Arkon P-70, Foral 85-E or Foral AX-E followed by AQ1045 were added and the mixing was continued for an additional 30 minutes. The heat supply was turned off and the mixing chamber 10 was cooled to 80°C. The pectin or Klucel was added and the mixing was continued in vacuo until a total mixing time of 90 minutes. The adhesive agent was removed from the mixer and pressed into 1 mm thin plates between two sheets of silicon paper in a hydraulic press at 90°C.

Table 3

| Constituent | Example 12 | Example 13 | Example 14 | Example 15 | Example 16 |
|-----------------|---------------|---------------|---------------|---------------|---------------|
| AQ1045 | 30 | 30 | 30 | 25 | 30 |
| LVSI 101 | 25 | 25 | 25 | 20 | 25 |
| Vector® 4114 | 5 | 5 | 5 | 12 | 5 |
| ArkoniP90 | 10 | 10 | | 13 | |
| Arkoni P70 | | | 10 | | |
| Foral 85-E | | | | | 10 |
| Foral AX-E | | | | | |
| Klucel HXF | 15 | | 15 | 15 | |
| Pektin | 15 | 30 | 15 | 15 | 30 |

Table 4

| Constituent | Example 17 | Example 18 | Example 19 | Example 20 | Example 21 |
|-----------------|---------------|---------------|---------------|---------------|---------------|
| AQ1045 | 30 | 35 | 35 | 35 | 40 |
| LVSI 101 | 25 | 25 | 30 | 25 | 20 |
| Vector® 4114 | 5 | 5 | 5 | 5 | 5 |
| ArkoniP90 | | 15 | 10 | 10 | 10 |
| Arkoni P70 | | | | | |
| Foral 85-E | | | | | |
| Foral AX-E | 10 | | | | |
| Klucel HXF | | | | | |
| Pektin | 30 | 20 | 20 | 25 | 25 |

CLAIMS

1. A pressure sensitive adhesive composition suitable for application to human or animal skin comprising a) a water dispersible polymer, b) one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, and/or one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, and/or one or more polyethylene glycols and/or glycerol; c) optionally a butene polymer or copolymer, d) optionally a tackifying resin which may be partly or totally hydrogenated, e) optionally a microcrystalline wax, f) optionally a plasticizer, g) optionally one or more hydrocolloids and h) optionally a pigment.
2. An pressure sensitive adhesive composition as claimed in claim 1, characterised in that it comprises 10-50% of a water dispersible polymer, 10-70% of one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, and/or one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, and/or one or more polyethylene glycols and/or glycerol; 0-15% of a butene polymer or copolymer, 0-30% of a tackifying resin which may be partly or totally hydrogenated, 0-10% of a microcrystalline wax, 0-10% of a plasticizer, 0-50% of one or more hydrocolloids and 0-5% of a pigment.
3. An adhesive composition as claimed in claim 1 or 2, characterised in that water dispersible polymer is a water-dispersible polyester.
4. An adhesive composition as claimed in claim 3, characterised in that water dispersible polymer is a water-dispersible branched polyester.
5. An adhesive composition as claimed in claim 4, characterised in that the branched polyester has a Brookfield Thermosel viscosity at 177°C of 1,000-500,000.

6. A method for preparing a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a) a water dispersible polymer, b) one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, and/or one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, and/or one or more polyethylene glycols and/or glycerol; c) optionally a butene polymer or copolymer, d) optionally a tackifying resin which may be partly or totally hydrogenated, e) optionally a microcrystalline wax, f) optionally a plasticizer, g) optionally one or more hydrocolloids and h) optionally a pigment, characterised in that the polymer selected from the group consisting of polyolefins or copolymers or blends thereof, one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more butadienes, polyethylene glycols and glycerol is mixed, whereafter the water dispersible polyester is admixed and mixed until homogeneity, a plasticizer is optionally admixed, and optionally one or more hydrocolloids are admixed under a reduced pressure whereafter the adhesive agent is removed from the mixer and optionally pressed into 1 mm thin plates between two sheets of release paper.

7. Use of a pressure sensitive adhesive composition suitable for application to human or animal skin comprising a) a water dispersible polymer, b) one or more polymer(s) selected from the group consisting of polyolefins or copolymers or blends thereof, and/or one or more physically cross-linked elastomers selected from block-copolymers comprising styrene and one or more olefins, and/or one or more polyethylene glycols and/or glycerol; c) optionally a butene polymer or copolymer, d) optionally a tackifying resin which may be partly or totally hydrogenated, e) optionally a microcrystalline wax, f) optionally a plasticizer, g) optionally one or more hydrocolloids and h) optionally a pigment for securing of and sealing around ostomy bandages, for securing wound dressings, for securing of devices for collecting urine, wound-drainage bandages, orthoses and prostheses and for protection skin areas and parts of the body against pressure, impacts and friction.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00229

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: C09J 167/00, C09J 123/00, C09J 125/08
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: C09J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CAPLUS

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☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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| "P" document published prior to the international filing date but later than the priority date claimed | |

| | |
|--|---|
| Date of the actual completion of the international search 2 Sept. 1998 | Date of mailing of the international search report 07-09-1998 |
| Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86 | Authorized officer Sofia Nikolopoulou Telephone No. +46 8 782 25 00 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00229**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

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